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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,599 | 12/12/2003 | Scott A. Meyer | GUID.142PA (03-100) | 1644 |
| 51294 | 7590 | 02/07/2006 | EXAMINER | |
| HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425 | | | JACKSON, BRYAN M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |
| DATE MAILED: 02/07/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/734,599 | Applicant(s) MEYER ET AL. | |
| | Examiner Bryan M. Jackson | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 30-61 is/are rejected.
- 7) ☒ Claim(s) 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/21/04 and 5/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 6/21/04 and 5/2/05 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 22, the limitation "pace up" is recited on line 2. There is insufficient antecedent basis for this limitation in the claim since "pace up" is not introduced in any previous claim on which claim 22 is dependent. It is suggested to change "pace up" to "back up" as in claim 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6-9, 13-14, 16-21, 23, 33, 35-43, 47-56, and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu (6275731). Zhu discloses that a

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pacing stimulus (fig 1,12) is delivered which evokes a response (fig 1,14), a first and second preset time considered to be a first and second detection window over a time range (claim 1), pulse amplitude --- considered to be a characteristic of a cardiac signal -- is compared to a predetermined threshold (col 1, ln 14-19), if an amplitude exceeds the first sensing threshold level then the controller triggers the second preset time and determines whether an intrinsic event occurs and if no intrinsic event occurs then a backup stimulation pulse is delivered (col 3, ln 49-58), changes in capture threshold may be detected by monitoring stimulation pulses at various energy levels (col 2, ln 5-7), wherein a capture threshold is considered to be a numeric value in units of pulse amplitude (i.e. voltage), detection of a "captured", "non-capture", "intrinsic", and "fusion" beats in a cardiac rhythm management device (fig 1), due to intrinsic detection latency a stimulation pulse may be delivered after intrinsic activation has already begun -- referred to as "pseudo-fusion" (col 2, ln 24-27), unipolar pacing stimulation (fig 1), and "conventional rhythm management devices may be designed to stimulate the ventricle, atrium or both the ventricles and atriums depending upon the heart abnormality" (col 1, ln 39-42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu (6275731).

Zhu discloses the claimed invention but does not disclose expressly the triggering one or more additional classification windows based on one or more additional trigger characteristics (claims 2 and 3). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the triggering of a second classification window if a trigger characteristic is detected in a first classification window, as taught by Zhu, with the triggering one or more additional classification windows based on one or more additional trigger characteristics, because Applicant has not disclosed that triggering one or more additional classification windows based on one or more additional trigger characteristics provides an advantage, is used for a particular purpose, or solve a stated problem.

Zhu discloses the claimed invention but does not disclose expressly the triggering one or more additional classification windows if a back up pacing stimulation is delivered (claim 22). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the triggering of a second classification window if a trigger characteristic is detected in a first classification window, as taught by Zhu, with the triggering one or more additional classification windows if a back up pacing stimulation is delivered, because Applicant has not disclosed that triggering one or more additional classification windows if a back up pacing stimulation is delivered provides an advantage, is used for a particular purpose, or solve a stated problem.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Housworth (5443485).

Zhu discloses the claimed invention but does not disclose expressly bipolar pacing stimulation. Housworth teaches that it is known to use bipolar pacing in a cardiac stimulator (col 4, ln 32-39). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the unipolar pacing stimulation (fig 1), as taught by Zhu, with the bipolar pacing stimulation in the same field of endeavor, because the Applicant has not disclosed that bipolar pacing stimulation provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the unipolar pacing stimulation, as taught by Zhu, because it provides a treatment for differing heart abnormalities, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Zhu.

Therefore, it would have been an obvious matter of design choice to modify Zhu to obtain the invention as specified in the claim(s).

Claims 10-11 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (20040127950) in view of Zhu. Kim discloses a "can electrode (fig 2, 209) and the SVC-coil electrode (fig 2, 116) may be shorted and a shock channel signal sensed as the voltage developed between the RV-coil 114 and the can electrode 209/SVC-coil 116 combination" (pg 4, para 0049).

Kim discloses the claimed invention except for the first and second classification window, wherein a trigger characteristic establishes the second classification window. Zhu teaches that it is known to have a first and second detection window and to compare a pulse amplitude to a predetermined threshold to trigger the second detection window (col 3, ln 49-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode configurations, as taught by Kim, with a first and second detection window and to compare a pulse amplitude to a predetermined threshold to trigger the second detection window, as taught by Zhu, in order to sense far-field cardiac signals.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Kim.

Zhu discloses the claimed invention except for the reduction of a pacing artifact signal (claim 12). Kim teaches that it is known to cancel a pacing artifact from a cardiac signal sensed following a pacing pulse via a pacing artifact template (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Zhu, with the cancellation of a pacing artifact from a captured cardiac signal, as taught by Kim, in order to provide an evoked cardiac response via the cancellation of a pacing artifact from a captured cardiac signal.

Claims 15 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Florio (6512953). Zhu discloses the claimed invention except for

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detecting a peak of the cardiac signal (claims 15 and 61). Florio teaches that it is known to use a morphology detector for peak detection, slope detection, waveform integration, and timing interval estimations of a cardiac signal (col 5, ln 5-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify device of Zhu, with peak detection, slope detection, waveform integration, and timing interval estimations of a cardiac signal, as taught by Florio, in order to improve the classification of cardiac responses via the characteristics of peak and slope detection.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu and Florio as applied to claim 15 above, and further in view of Schroeppel (5431693).

Zhu and Florio disclose the claimed invention except for the detection of an intrinsic cardiac event in a first classification window (claims 24 and 25). Schroeppel teaches that it is known to detect an intrinsic cardiac response in a first time window (col 7, ln 2-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses via detecting a peak, as taught by Zhu and Florio, with the detection of an intrinsic cardiac event in a first classification window, as taught by Schroeppel, in order to provide a means for differentiating between different types of cardiac responses.

Zhu and Florio disclose the claimed invention except for the detection of a fusion/pseudofusion cardiac response within a first classification window (claims 26 and

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27). Zhu and Florio teach that it is known to deliver a pacing pulse during an intrinsic event due to intrinsic detection latency (pseudofusion) and detect a peak of a cardiac signal, respectively. Zhu and Florio do not explicitly state that a fusion/pseudofusion cardiac response is detected within a first classification window, but it appears that detection of a fusion/pseudofusion within a first classification window is used to provide a means for differentiating between different types of cardiac responses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery of a pacing pulse during an intrinsic event due to intrinsic detection latency (psuedofusion) and detection of a peak of a cardiac signal, respectively, as taught by Zhu and Florio, with the detection of an intrinsic cardiac event in a first time window, as taught by Schroepfel, in order to provide the detection of fusion/psuedofusion cardiac response within a first time window.

Claims 30, 34, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Housworth (5443485). Zhu discloses the claimed invention except for the detection of a captured cardiac response within a second classification window. Housworth teaches that it is known to detect a captured response in a second window in order to differentiate between captured and intrinsic cardiac responses (col 9, ln 4-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of captured cardiac responses in a first detection window, as taught by Zhu, with the detection of a

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captured response in a second window, as taught by Housworth, in order to provide a means for differentiating between different types of cardiac responses.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu and Florio, as applied to claim 15 above, and further in view of Housworth (5443485).

Zhu and Florio disclose the claimed invention except for the detection of a captured cardiac response within a second classification window (claims 31-32). Housworth teaches that it is known to detect a captured response in a second window in order to differentiate between captured and intrinsic cardiac responses (col 9, ln 4-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses in a first detection window via detecting a peak, as taught by Zhu and Florio, with detection of a captured response in a second window, as taught by Housworth, in order to provide a means for differentiating between different types of cardiac responses.

Allowable Subject Matter

Claims 28-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

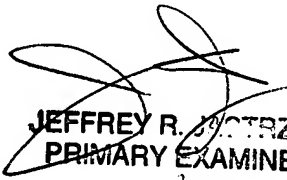
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Greenhut (20020138111) discloses a stimulation arrangement with stimulation success monitoring. KenKnight (6169921) discloses an autocapture determination for an implantable cardioverter defibrillator. Zhu (6192275/6505071) discloses an adaptive evoked response sensing for automatic capture verification, and a cardiac management device with capability of noise detection in automatic capture verification. Florio (6324427/6618619) discloses an implantable cardiac stimulation device having T-wave discrimination of fusion events during autocapture/autothreshold assessment, and a method and apparatus for reducing the effect of evoked responses on polarization measurements in an automatic capture pacing system. Lee (20040243014) discloses a cardiac waveform template creation, maintenance and use. Vonk (6567701) discloses a method and system for discriminating captured beats from non-captured beats in a cardiac pacing system. Bradley (20030050671) discloses a Method and device for enhanced capture tracking by discrimination of fusion beats. Juran (6466820) discloses a multi-site cardiac pacing system having trigger pace window.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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PRIMARY EXAMINER
2/3/04